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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,809	01/18/2000	Julio J. Santos-Munne	4204.3-US	1128

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EXAMINER

MILLER, RYAN J

ART UNIT	PAPER NUMBER
2621	

DATE MAILED: 10/03/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/484,809	SANTOS-MUNNE ET AL.
Examiner	Art Unit	
Ryan J. Miller	2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on \_\_\_\_.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 1-10 is/are rejected.

7) Claim(s) \_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 18 January 2000 is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.	6) <input type="checkbox"/> Other: ____.

## **DETAILED ACTION**

The examiner acknowledges the preliminary amendment filed on February 15, 2001.

### *Drawings*

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: (a) “103” in Fig. 4, (b)“300” referring to a screen in Fig. 6, (c) “606” referring to a projected stent in Fig. 9, and (d) “606” in Fig. 7. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Claim Objections*

1. Claim 3 is objected to because of the following informalities: mentions “lines of site” instead of “lines of sight”. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 6-8 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Peshkin et al., U.S. Patent No. 5,799,055. As applied to claim 6, Peshkin et al. discloses the step of displaying a first fluoroscopic image taken of an anatomical feature taken from a first pose, the first image being registered to a common three-dimensional coordinate system (see Figs. 1 and 3a and column 5, lines 14-29). The reference describes using a fluoroscope to take an image of a patient's body and then displaying the image on graphics monitor 48. The reference goes on to describe registering the image by creating a geometric model projecting three-dimensional coordinates into image points (i.e. the first image being registered to a common). Peshkin et al. discloses the next step of receiving indication of position within first image of a projected surgical object corresponding to a three-dimensional virtual object, the virtual surgical object being defined with reference to the common three-dimensional coordinate system and having one or more attributes corresponding to one or more physical characteristics of a surgical object to be implanted in the patient (see column 5, lines 43-54). The reference describes receiving the position, length, and angle of a virtual guidewire in the image (i.e. receiving indication of position within first image of a projected surgical object corresponding to a three-dimensional virtual object). The reference further describes that the virtual guidewire has to be constrained to correspond geometrically to the same three-dimensional segment in space (i.e. the virtual surgical object being defined with reference to the common three-dimensional coordinate system) and the virtual guidewire has a length, which constitutes a physical characteristic. Peshkin et al. further discloses displaying a second fluoroscopic image taken of the anatomical

feature from a second angle, the second image being registered to the known three-dimensional coordinate system (see Figs. 1 and 3b and column 5, lines 30-41). The reference discloses obtaining a second image of the patient's body from a different angle and displaying it on graphics display 50. A geometric model is then obtained for the second image by projecting three-dimensional coordinates into image points (i.e. the second image being registered to the known three-dimensional coordinate system). Peshkin et al. then discloses the step of drawing on the first and second fluoroscopic images two-dimensional projections of the virtual surgical object (see column 5, lines 55-67 and column 6, lines 1-4). The reference describes moving either end of the virtual guidewire, changing its length, and/or changing its angle, by redrawing the guidewire on one of the images (i.e. drawing on the first and second fluoroscopic images two-dimensional projections of the virtual surgical object). Peshkin et al. also discloses the step of updating on the projection of the virtual surgical object in the drawing on the first and second fluoroscopic images two-dimensional projections of the virtual surgical object in response to a user manipulating the projection of the virtual surgical object in the second image (see column 9, lines 4-13). The reference describes a surgeon (i.e. a user) choosing lines on the A/P image (i.e. the first fluoroscopic image's two-dimensional projection of the virtual surgical object) and having them immediately displayed on the sagittal image (i.e. the second fluoroscopic image's two-dimensional projection of the virtual surgical object). This corresponds to updating the projection of the virtual surgical object in the drawing.

As applied to claim 7, Peshkin et al. discloses that the step of manipulating the projection of the virtual surgical object includes moving the projection to a point where it best aligns with an anatomical feature shown in the image (see Fig. 14 and column 15, lines 37-67). The

reference describes moving the robot's end-effector to the correct position and angle of the virtual guidewire (i.e. the projection of the virtual surgical object). The correct position and angle corresponds to a point where a surgery is going to take place (i.e. a point where it best aligns with an anatomical feature shown in the image).

As applied to claim 8, Peshkin et al. discloses that the step of manipulating the projection of the virtual surgical object includes modifying a dimension of the virtual surgical object to align the projection with an anatomical feature in shown in the image (see Figs. 10-13). The previously mentioned figures describe methods for determining and changing various values of the dimensions of the virtual guidewire including the transverse angle, the length, the orientation, and the approach angle.

As applied to claim 10, which merely calls for a computer readable storage medium on which is recorded program instructions for performing the method of claim 6, such a computer readable storage medium is inherent to Peshkin et al. since all of the processing in the reference is performed by computer.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peshkin et al. in view of Kano, U.S. Patent No. 4,099,880. The arguments as to the relevance of Peshkin et al. in paragraph 2 above are incorporated herein. Claim 1 calls for three steps that are absent from

Peshkin et al. These steps include 1) receiving indication of position of at least a first point and a second point within first image corresponding respectively to at least two anatomical landmarks shown within first image, 2) indicating with reference to the second image where the anatomical landmarks lie along each of two lines of sight defined by the first and second points within the three-dimensional coordinate system, and 3) determining distance of a line specified by the first and second points. These steps are clearly shown in Kano. Kano describes determining points A and B of a subject which can be seen in Fig. 2 as corresponding to some anatomical landmark. Kano further describes determining where the anatomical landmarks lie along each of two lines of sight. This can be clearly seen by lines A1-B1 and A2-B2 in two separate images in Fig. 2. Kano also describes determining the distance between points A and B in the subject (see column 3, lines 6-30). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Peshkin et al. by adding the additional steps of Kano because the method presented by Kano is "highly effective for diagnosing an affected part in a human body. The shape and position of the affected part can be accurately measured in advance before the operation and therefore the operation can be performed precisely and efficiently" (see Kano: column 10, lines 43-47).

Claim 2 calls for placing within the field of view of each fluoroscopic image a plurality of fiducials having known positions with respect to each other; receiving an input to identify two-dimensional coordinates of each of the plurality of fiducials displayed on each of the images; and registering the images by creating a geometric model having parameters, said model projecting three-dimensional coordinates of the plurality of fiducials into the identified coordinates of the fiducials on the images, and numerically optimizing the parameters of the

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geometric model such that the projections of the known three-dimensional coordinates of the fiducials best fit the identified two-dimensional coordinates in each of the images. Peshkin et al. describes a registration artifact containing a plurality of features (fiducials) having positions known relative to a coordinate system fixed in the artifact (see column 2, lines 59-65). The reference also describes inputting two-dimensional locations of the projections of the fiducials in the fluoroscopic images (see column 2, lines 66-67). The reference also describes determining “the geometric projections that carry a general three-dimensional point anywhere in the vicinity of the artifact into a projected point on the image. This establishes registration between image and workspace. Several images can each be registered relative to the same registration artifact, thus also bringing all the images into registry with one another” (see column 3, lines 1-6). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use fiducials in the registration process because it allows “surgeons to acquire fluoroscopic images using fluoroscope poses of their own choosing, as they are accustomed” (see Peshkin et al.: column 2, lines 55-58).

Claim 3 calls for the lines of sight on the second image to be drawn by lines on the second image. This process can be clearly seen in Figs. 3a and 3b of Peshkin et al. These figures show lines of sight, 92 and 68 respectively, connecting points 88 and 90 in Fig. 3a and 64 and 66 in Fig. 3b. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to draw in the lines of sight because this addition to the fluoroscopic images would allow for doctors to more accurately determine the positions of features such as tumors in the image.

As applied to claim 4, which calls for an apparatus to perform the method of claim 1, since Peshkin et al. in view of Kan disclose the method then it is inherent that an apparatus for performing the method is also anticipated.

As applied to claim 5, which calls for a computer readable storage medium on which is recorded program instructions for performing the method of claim 1, such a computer readable storage medium is inherent to Peshkin et al. in view of Kano since all of the processing in the reference is performed by computer.

4. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peshkin et al. in view of Alt, U.S. Patent No. 6,159,142. The arguments as to the relevance of Peshkin et al. in paragraph 2 above are incorporated herein. Claim 9 calls for the virtual surgical object to be a stent. A stent is absent from Peshkin et al. but is clearly shown in Alt (see column 1, lines 57-64). Alt describes a process of implanting a stent under fluoroscopic observation. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Peshkin et al. by adding the stent of Alt because the use of fluoroscopic imaging when implanting stents is widespread. Therefore, a method for planning this surgery through the use of fluoroscopic images and virtual stents is very important for increasing the safety and reliability of such procedures.

#### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Gueziec et al., United States Patent No. 5,951,475, describes a method of registering fluoroscopic images containing radio-opaque markers.

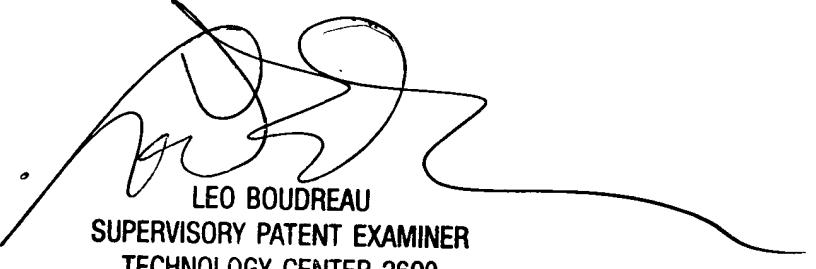
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Miller whose telephone number is (703) 306-4142. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9314.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4750.

Ryan J. Miller  
Examiner  
Art Unit 2621

Ryan J. Miller  
September 30, 2002



LEO BOUDREAU  
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